K073677

510(k) Summary of Substantial Equivalence
Aperio Technologies, Inc.
(ScanScope® XT System)

AUG 11 2008

21 CFR 807.92(a):

21 CFR 807.92(a) (1):

Submitter's name and address:

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Date this 510(k) summary was prepared:

July 1, 2008

21 CFR 807.92(a)(2):

Trade Name of Device:	ScanScope® XT System
Regulatory Section:	21 CFR 864.1860 Immunhistochemistery reagents and kits
Classification:	Class II
Product Code:	NQN (Microscope, Automated, Image Analysis, immunohistochemistry, Operator Intervention, Nuclear Intensity and Percent Positivity)

21 CFR 807.92(a)(3): Legally marketed predicate device to which substantial equivalence is claimed:

Predicate Device:	Applied Imaging Ariol™ with ER/PR Application
Manufacturer:	Applied Imaging Coporation
Predicate Device k#:	k033200

21 CFR 807.92(a)(4): Description of the device that is the subject of this premarket notification:

System: The system comprises a ScanScope® XT digital slide scanner instrument and a computer system executing Spectrum™ software. The system capabilities include digitizing microscope slides at diagnostic resolution, storing and managing the resulting digital slide images, retrieving and displaying digital slides, including support for remote access over wide-area networks, providing facilities for annotating digital slides and entering and editing metadata associated with digital slides, and facilities for image analysis of digital slides, including the ability to quantify characteristics useful to Pathologists, such as measuring and scoring immunohistochemical stains applied to histology specimens, such as Dako ER/PR, which reveal the presence of ER (Estrogen Receptor) protein and PR (Progesterone Receptor) protein expression, which may be used to determine patient treatment for breast cancer.

Hardware Operation: The ScanScope XT digital slide scanner creates seamless true color digital slide images of entire glass slides in a matter of minutes. A high numeric aperture 20x, as found on conventional microscopes, is used to produce high-quality images. (When the 2X magnification changer is inserted, the effective magnification of the images is 40X.) The ScanScope XT employs a linear-array scanning technique that generates images free from optical aberrations along the scanning axis. The result is digital slide images that have no tiling artifacts and are seamless.

Software Operation: The Spectrum software is a full-featured digital pathology management system. The software runs on a server computer called a Digital Slide Repository (DSR), which stores digital slide images on disk storage such as a RAID array, and which hosts an SQL database that contains digital slide metadata. Spectrum includes a web application and services which encapsulate database and digital slide image access for other computers. The Spectrum server supports the capability of running a variety of image analysis algorithms on digital slides, and storing the results of analysis into the database. Spectrum also includes support for locally or remotely connected image workstation computers, which run digital slide viewing and analysis software provided as part of Spectrum.

Overview of System Operation: The laboratory technician or operator loads glass microscope slides into a specially designed slide carrier with a capacity of up to 120 slides. The scanning process begins when the operator starts the ScanScope scanner and finishes when the scanner has completed scanning of all loaded slides. As each glass slide is processed, the system automatically stores individual "striped" images of the tissue contained on the glass slide and integrates the striped images into a single digital slide image, which represents a histological reconstruction of the entire tissue section. After scanning is completed, the operator is able to view and perform certain analytical tests on the digital slides.

21 CFR 807.92(a)(5): Intended use and labeled indications for use:

The ScanScope® XT System is an automated digital slide creation, management, viewing and analysis system.

It is intended for *in vitro* diagnostic use as an aid to the pathologist in the display, detection, counting and classification of tissues and cells of clinical interest based on particular color, intensity, size, pattern and shape.

The IHC ER Image Analysis application is intended for use as an aid to the pathologist in the detection and quantitative measurement of ER (Estrogen Receptor) in formalin-fixed paraffin-embedded normal and neoplastic tissue.

The IHC PR Image Analysis application is intended for use as an aid to the pathologist in the detection and quantitation measurement of PR (Progesterone Receptor) in formalin-fixed, paraffin-embedded normal and neoplastic tissue.

It is indicated for use as an aid in the management, prognosis, and prediction of therapy outcomes of breast cancer.

Note: The IHC ER and PR Image Analysis applications are an adjunctive computer-assisted methodology to assist the reproducibility of a qualified pathologist in the acquisition and measurement of images from microscope slides of breast cancer specimens stained for the presence of estrogen and progesterone receptor proteins. The accuracy of the test result depends upon the quality of the immunohistochemical staining. It is the responsibility of a qualified pathologist to employ appropriate morphological studies and controls as specified in the instructions for the ER and PR reagent/kit used to assure the validity of the IHC ER and PR Image Analysis application assisted scores.

21 CFR 807.92(a)(6): Technological characteristics:

The design, construction, energy source and other characteristics of the ScanScope System candidate device are considered to be substantially equivalent to the relevant features of the predicate device. A summary of the technological characteristics of the ScanScope System candidate device in comparison to the predicate device follows:

Method of cell detection. The method of cell detection is by colorimetric and morphometric pattern recognition by microscopic examination of prepared cells by size,

shape, color, and intensity as observed by a computer-automated, microscopic digital slide scanner system and/or by visual observation by a health care professional.

System Components. The system components comprising the ScanScope System candidate device are substantially equivalent to those in the predicate device; i.e., a computer-automated digital microscope slide scanner, computer, color monitor, and keyboard.

Energy Source. The electrical service is 100vAC – 240vAC, 50Hz/60 Hz, 2 amps which is similar to the predicate device electrical service requirements.

21 CFR 807.92(b): 510(k) summaries for those premarket submissions in which determination of substantial equivalence is also based on an assessment of performance data shall contain the following information:

21 CFR 807.92(b)(1): Brief discussion of non-clinical tests submitted, referenced or relied on in this premarket notification:

There are no non-clinical tests submitted, referenced or relied on in this submission.

21 CFR 807.92(b)(2): Brief discussion of clinical tests submitted, referenced or relied on in this premarket notification:

Comparison studies:

a. Method comparison with predicate device:

The substantial equivalence study was based on comparison of image analysis to conventional manual microscopy. Manual microscopy was performed in accordance with the reagent vendor's instructions for use.

Two Clinical Laboratory Improvement Amendments (CLIA) qualified clinical sites participated in the study. Prior to their participation in the study each clinical site obtained exemption status from an Institutional Review Board (IRB).

The first clinical site participated in the ER study.

A total set of 80 formalin-fixed, paraffin-embedded breast tissue specimens from the first clinical site was used for the ER study.

The specimens at the first clinical site were selected based on their clinical scores on file to provide an equal distribution of ER slides in the percentage of positive nuclei ranges 0%, 1% to 4%, 5% to 9%, 10% to 49%, and 50% to 100%.

All specimens for the ER study were immunohistochemically stained at the first clinical site using Dako in vitro diagnostic (IVD) FDA cleared Monoclonal Mouse Anti-Human Estrogen Receptor α (Clone 1D5) (K993957).

Both clinical sites participated in the PR study.

A total set of 180 formalin-fixed, paraffin-embedded breast tissue specimens from both clinical sites were used for the PR study; 80 slides from the first clinical site and 100 slides from the second clinical site.

The specimens at the first clinical site were selected based on their clinical scores on file to provide an equal distribution of PR slides in the percentage of positive nuclei ranges 0%, 1% to 4%, 5% to 9%, 10% to 49%, and 50% to 100%. The specimens at the second clinical site were routine specimens taken from their clinical operation, representing the true target population of cases in a typical clinical setting.

All specimens for the PR study were immunohistochemically stained at the clinical sites using Dako in vitro diagnostic (IVD) FDA cleared Monoclonal Mouse Anti-Human Progesterone Receptor (Clone PgR 636) (K020023).

The study was performed primarily at the participating clinical sites and all parts except the scanning of glass slides were performed at their facilities using their typical workflow. The glass slides were prepared in the sites' clinical laboratories and read by board certified staff pathologists. For the scanning of glass slides ScanScope XT instruments were operated in a simulated clinical setting at Aperio (designed to be representative of a typical lab environment).

All ScanScope XT instruments used in the study were production units and were delivered, installed, and maintained in accordance with the approved procedures, per Aperio's QSPs (Quality Systems Procedures), and as described in product documentation and labeling.

Three different board-certified pathologists at each clinical site performed a blinded manual review of each glass slide using a conventional light microscope. The pathologists reported the percentage of positive nuclei [0%, 1%, ... 100%] and average intensity score of 0, 1+, 2+ or 3+ for each of the reviewed glass slides.

Based on the manual microscopy average percentages of positive nuclei from the three pathologists, the glass slides used for the ER study provided the following percentages of positive nuclei distribution.

Percentage	Clinical Site 1
0%	31
[1%- 5%)	2
[5%-10%)	2
[10%-50%)	8
[50%-100%]	37
Total	80

ER Percentage of Positive Nuclei Distribution.

Based on the manual microscopy average intensity scores from the three pathologists, the glass slides used for the ER study provided the following average intensity score distribution.

Intensity Score	Clinical Site 1
0	29
1+	8
2+	24
3+	19
Total	80

ER Average Intensity Score Distribution.

Based on the manual microscopy average percentages of positive nuclei from the three pathologists, the glass slides used for the PR study provided the following percentages of positive nuclei distribution.

Percentage	Clinical Site 1	Clinical Site 2	Total
0%	29	33	62
[1%- 5%)	12	6	18
[5%-10%)	8	3	11
[10%-50%)	15	11	26
[50%-100%]	16	47	63
Total	80	100	180

PR Percentage of Positive Nuclei Distributions.

Based on the manual microscopy average intensity scores from the three pathologists, the glass slides used for the PR study provided the following average intensity score distribution.

Intensity Score	Clinical Site 1	Clinical Site 2	Total
0	26	31	57
1+	14	3	17
2+	20	12	32
3+	20	54	74
Total	80	100	180

PR Average Intensity Score Distributions.

As it can be seen from the ER and PR percentage of positive nuclei distributions, it was not possible to obtain an equal distribution of the percentage of positive nuclei in the range from 1% to 10%. This difficulty was founded in the limited representation of this percentage range in the true target population of cases.

All glass slides were scanned using a different ScanScope XT instrument for each clinical site.

After a wash-out period of over one week and subsequent randomization of the slides, the same three pathologists at each clinical site outlined a representative set of tumor regions for each digital slide using the ScanScope Systems' remote editing capability. The pathologists' annotations of tumor region outlines were blinded from each other.

Image analysis was performed on each slide for each of the different sets of tumor regions outlined by the three pathologists, resulting in a separate image analysis score for each of the three pathologists. Image analysis was run in batch processing mode completely separated from the pathologists outlining the tumor regions to avoid influencing the pathologists in their choice of tumor regions. The image analysis algorithm reported the percentage of positive nuclei [0.0%, ... 100.0%] and average intensity score of 0, 1+, 2+ or 3+ for each of the digital slides.

The statistical analyses are presented for ER and PR for each of the scores: percentage of positive nuclei and intensity scores. The statistical analyses are presented across all slides for manual microscopy and image analysis, and comparatively between the two methods for the clinical sites with their different three pathologists.

Estrogen Receptor (ER)

Percentage of Positive Nuclei

The inter-pathologist agreements for the performed (blinded) image analysis were in the range of 93.8%-98.8% and the inter-pathologist agreements for manual microscopy were in the range of 91.3%-98.8%.

The agreements between the pathologists' manual microscopy and performed (blinded) image analysis were in the range of 92.5%□97.5% and the inter□pathologist agreements for manual microscopy were in the range of 91.3%□98.8%.

Intensity Score

The inter-pathologist agreements for the performed (blinded) image analysis were in the range of 88.8%-90.0% and the inter-pathologist agreements for manual microscopy were in the range of 55.0% - 86.3%.

The agreements between the pathologists' manual microscopy and performed (blinded) image analysis were in the range of 63.8%□86.3% and the inter□pathologists agreements for manual microscopy were in the range of 55.0% □ 86.3%.

Progesterone Receptor (PR)

Percentage of Positive Nuclei

The inter-pathologist agreements for the performed (blinded) image analysis were in the range of 85.0%-99.0% and the inter-pathologist agreements for manual microscopy were in the range of 83.8%-99.0%.

The agreements between the pathologists' manual microscopy and performed (blinded) image analysis were in the range of 81.3%-99.0% and the inter-pathologists agreements for manual microscopy were in the range of 83.8%-99.0%.

Intensity Score

The inter-pathologist agreements for the performed (blinded) image analysis were in the range of 68.8%-88.0% and the inter-pathologist agreements for manual microscopy were in the range of 58.8%-88.0%.

The agreements between the pathologists' manual microscopy and performed (blinded) image analysis were in the range of 58.8%-84% and the inter-pathologists agreements for manual microscopy were in the range of 58.8%-88.0%.

Note that these image analysis results were obtained by having the Pathologists choose and outline a representative set of tumor regions anywhere on the entire slide, completely blinded from each other, and blinded from the image analysis

results (there was no influence on the Pathologists in their choice of the tumor regions).

Analytical Performance:

a. Precision:

The precision of the ScanScope XT System was suite of intra-run/intra-system, inter-run/intra-system, inter-system and intra-pathologist studies.

12 ER and 10 PR slides from the comparison study were used for this study. Using the same slides from the comparison study allowed the results obtained in the precision studies to be placed into perspective by comparing them to the inter-pathologist results. The ER slides consisted of formalin-fixed, paraffin-embedded breast tissue specimens immunohistochemically stained using Dako in vitro diagnostic (IVD) FDA cleared Monoclonal Mouse Anti-Human Estrogen Receptor α (Clone 1D5) (K993957).

The PR slides consisted of formalin-fixed, paraffin-embedded breast tissue specimens immunohistochemically stained using Dako in vitro diagnostic (IVD) FDA cleared Monoclonal Mouse Anti-Human Progesterone Receptor (Clone PgR 636) (K020023).

10 ER and 10 PR were selected to provide an equal distribution of slides in the percentage of positive nuclei ranges 0%, 1% to 4%, 5% to 9%, 10% to 49%, and 50% to 100% (two slides in each of the identified ranges) using the average percentage of positive nuclei from the three pathologists in the comparison study.

The pathologists' selection of tumor regions for image analysis introduces some variability to the system. To properly assess the true variability of the system the influence of the pathologists' selections in the intra-run/intra-system, inter-run/intra-system, and inter-systems studies was eliminated by using the same tumor regions for image analysis of all scans of the same slide.

The image analysis algorithm reported the percentage of positive nuclei [0.0%, … 100.0%] and average intensity score of 0, 1+, 2+, or 3+ as well as the underlying average intensity on a scale from 0 to 255.

The statistical analyses are presented for ER and PR for the percentage of positive nuclei and intensity scores.

Intra- system: The slide scores provided by image analysis over 10 consecutive scans were analyzed for all 10 ER and 10 PR slides.

Estrogen Receptor (ER)

Percentage of Positive Nuclei

The image analysis results show an overall standard deviation of 0.31% (maximum 0.74%) and average range (maximum – minimum) of 0.71% (maximum 2.25%) for the percentage of positive nuclei [0.0-100.0%] across all runs.

Intensity Scores

The image analysis results show an overall standard deviation of 0.67 (maximum 1.45) and average range (maximum – minimum) of 1.18 (maximum 4.88) for the intensity values [0-255] across all runs.

Progesterone Receptor (PR)

Percentage of Positive Nuclei

The image analysis results show an overall standard deviation of 0.54% (maximum 1.47%) and average range (maximum – minimum) of 1.06% (maximum 4.78%) for the percentage of positive nuclei [0.0-100.0%] across all runs.

Intensity Scores
The image analysis results show an overall standard deviation of 0.9 (maximum 1.60) and average range (maximum – minimum) of 2.48 (maximum 4.27) for the intensity values [0-255] across all runs.

Inter-system: The slide scores provided by image analysis over 10 consecutive scans on three different ScanScope XT instruments were analyzed for all 10 ER and 10 PR slides.

Estrogen Receptor (ER)

Percentage of Positive Nuclei

The image analysis results on each of the three ScanScope systems show an overall average standard deviation of 0.31%, 0.31% and 0.35% (maximum 0.74%, 0.65%, 0.84%) and average range of 0.71%, 0.70% and 0.81% (maximum 2.25%, 2.38%, 2.93%) for the percentage of positive nuclei [0.0-100.0%] across all runs.

The image analysis results of the three ScanScope systems combined show an overall average standard deviation of 0.55% (maximum 1.05%) and average range of 1.44% (maximum 4.02%) for the percentage of positive nuclei [0.0-100.0%] across all runs.

The image analysis results show minimal variation from one ScanScope system to another as shown in the following table that shows the mean over all runs of the reported percentage of positive nuclei [0.0-100.0%] for the 12 ER slides (#S) for the three ScanScope systems.

	S#1	S#2	S#3	S#4	S#5	S#6	S#7	S#8	S#9	S#10	S#11	S#12
ScanScope #1	0.06	0.10	0.12	0.16	0.27	0.34	25.20	25.83	82.70	91.24	6.27	3.13
ScanScope #2	0.06	0.08	0.11	0.15	0.25	0.34	24.84	24.58	83.12	91.60	6.74	3.47
ScanScope #3	0.05	0.07	0.11	0.08	0.27	0.31	24.06	23.50	81.00	90.20	6.70	3.41

Intensity Scores

The image analysis results on each of the three ScanScope systems show an overall average standard deviation of 0.67%, 0.72%, and 0.59% (maximum 1.45%, 2.08%, 1.33%) and average range of 1.18%, 1.33%, and 1.10% (maximum 4.88%, 6.85%, 4.18%) for the intensity values [0-255] across all runs.

The image analysis results of the three ScanScope systems combined show an overall average standard deviation of 1.22% (maximum 3.07%) and average range of 2.37% (maximum 8.91%) for the intensity values [0-255] across all runs.

The image analysis results show minimal variation from one ScanScope system to another as shown in the following table that shows the mean over all runs of the reported percentage of positive nuclei [0.0-100.0%] for the 12 ER slides (#S) for the three ScanScope systems.

	S#1	S#2	S#3	S#4	S#5	S#6	S#7	S#8	S#9	S#10	S#11	S#12
ScanScope #1	N/A	N/A	N/A	N/A	N/A	N/A	176.21	191.33	158.74	127.44	196.8	200.9
ScanScope #2	N/A	N/A	N/A	N/A	N/A	N/A	180.38	191.31	158.84	131.00	197.1	201.3
ScanScope #3	N/A	N/A	N/A	N/A	N/A	N/A	180.61	191.07	160.55	134.14	196.1	201.1

Progesterone Receptor (PR)

Percentage of Positive Nuclei

The image analysis results on each of the three ScanScope systems show an overall average standard deviation of 0.54%, 0.53% and 0.75% (maximum 1.47%, 1.23%, 2.05%) and average range of 1.06%, 1.23%, and 1.50% (maximum 4.78%, 4.17%, 7.20%) for the percentage of positive nuclei [0.0-100.0%] across all runs.

The image analysis results of the three ScanScope systems combined show an overall average standard deviation of 0.87% (maximum 1.57%) and average range of 2.54% (maximum 8.13%) for the percentage of positive nuclei [0.0-100.0%] across all runs.

The image analysis results show minimal variation from one ScanScope system to another as shown in the following table that shows the mean over all runs of the reported percentage of positive nuclei [0.0-100.0%] for the 10 PR slides (#S) for the three ScanScope systems.

	S#1	S#2	S#3	S#4	S#5	S#6	S#7	S#8	S#9	S#10
ScanScope #1	0.00	0.11	0.20	1.54	3.72	12.77	18.14	35.01	46.90	73.09
ScanScope #2	0.00	0.12	0.14	1.59	4.44	12.64	17.75	35.21	47.28	72.15
ScanScope #3	0.00	0.13	0.10	1.52	2.52	10.34	18.00	33.13	45.72	71.06

Intensity Scores

The image analysis results on each of the three ScanScope systems show an overall average standard deviation of 0.9%, 1.01%, and 0.93% (maximum 1.60%, 1.64%, 1.48%) and average range of 2.48%, 2.62%, and 2.60% (maximum 4.27%, 5.09%, 4.85%) for the intensity values [0-255] across all runs.

The image analysis results of the three ScanScope systems combined show an overall average standard deviation of 1.35% (maximum 2.03%) and average range of 4.55% (maximum 6.86%) for the intensity values [0-255] across all runs.

The image analysis results show minimal variation from one ScanScope system to another as shown in the following table that shows the mean over all runs of the reported percentage of positive nuclei [0.0-100.0%] for the 10 PR slides (#S) for the three ScanScope systems.

	S#1	S#2	S#3	S#4	S#5	S#6	S#7	S#8	S#9	S#10
ScanScope #1	N/A	N/A	N/A	160.10	203.65	191.84	186.11	176.15	148.62	139.88
ScanScope #2	N/A	N/A	N/A	160.00	204.05	191.61	184.07	175.62	149.26	141.15
ScanScope #3	N/A	N/A	N/A	160.45	202.57	191.68	185.53	175.91	152.69	143.52

21 CFR 807.92(b)(3): Conclusions drawn from the non-clinical and clinical tests: Based on the results of the clinical studies described in this 510(k) submission, it is concluded that the ScanScope System device is as safe and effective (therefore substantially equivalent) as the predicate device as an aid in the management, prognosis, and prediction of therapy outcomes of breast cancer.

....End of 510(k) Summary....

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 11 2008

Aperio Technologies, Inc.
c/o Mr. Jeff Ryberg
Director of Quality, Regulatory and Clinical
1360 Park Center Drive
Vista, CA 92081

Re: k073677
Trade/Device Name: ScanScope® XT System - IHC ER/PR Breast Tissue Image Analysis
Regulation Number: 21 CFR 864.1860
Regulation Name: Immunohistochemistry reagents and kits
Regulatory Class: Class II
Product Code: NQN
Dated: July 25, 2008
Received: July 28, 2008

Dear Mr. Ryberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

maria M Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073677

Device Name: ScanScope® XT System

Indications for Use:

The ScanScope® XT System is an automated digital slide creation, management, viewing and analysis system. It is intended for *in vitro* diagnostic use as an aid to the pathologist in the display, detection, counting and classification of tissues and cells of clinical interest based on particular color, intensity, size, pattern and shape.

The IHC ER Image Analysis application is intended for use as an aid to the pathologist in the detection and quantitative measurement of ER (Estrogen Receptor) in formalin-fixed paraffin-embedded normal and neoplastic tissue.

The IHC PR Image Analysis application is intended for use as an aid to the pathologist in the detection and quantitation measurement of PR (Progesterone Receptor) in formalin-fixed, paraffin-embedded normal and neoplastic tissue.

It is indicated for use as an aid in the management, prognosis, and prediction of therapy outcomes of breast cancer.

Note: The IHC ER and PR Image Analysis applications are an adjunctive computer-assisted methodology to assist the reproducibility of a qualified pathologist in the acquisition and measurement of images from microscope slides of breast cancer specimens stained for the presence of estrogen and progesterone receptor proteins. The accuracy of the test result depends upon the quality of the immunohistochemical staining. It is the responsibility of a qualified pathologist to employ appropriate morphological studies and controls as specified in the instructions for the ER and PR reagent/kit used to assure the validity of the IHC ER and PR Image Analysis application assisted scores.

Prescription Use ___X___ (Part 21CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety 510(k) K073677